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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,213	01/17/2006	Jonathan Lightner	7896-71292-08	5168
74051 7590 04/28/2008 Klarquist Sparkman, LLP 121 SW Salmon St., Floor 16 Portland, OR 97204				
EXAMINER MCILWAIN, ELIZABETH F				
ART UNIT		PAPER NUMBER		
1638				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/539,213

**Applicant(s)**

LIGHTNER ET AL.

**Examiner**

Elizabeth F. McElwain

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)  
Paper No(s)/Mail Date 6/23/06 4/6/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-8, in the reply filed on February 4, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-11 are withdrawn, as drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1 and 6, and claims 2-5, 7 and 8 dependent thereon, are indefinite in the recitation of "or an ortholog thereof" with regard to SEQ ID NO: 2. The specification at page 11 defines orthologs of HIO30 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO30 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity, and

preferably a pseudouridylate synthase domain. However, the list of possible functional activities is open ended, and most of the activities listed are generic, such as catalytic activity, binding activity, and signaling activity, wherein these functional activities are found in many divergent polypeptides that are not associated with producing a high oil phenotype in a plant. In addition, the specification does not set forth any protein motifs or 3-dimensional structure that would identify an ortholog of HIO30. Thus, the use of "ortholog" in the claim does not set forth the metes and bounds of the claimed invention.

5. Claims 1 and 6, and claims 2-5, 7 and 8 dependent thereon, are indefinite in the recitation of "high oil phenotype relative to control plants" and "altered oil content phenotype relative to control plants", given that it is unclear what is encompassed by "control plant" and the specification fails to set forth the metes and bounds of this term.

#### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to transgenic plants comprising a plant transformation vector

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comprising a sequence that encodes HIO30 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or an ortholog thereof, and wherein the plant has a high oil phenotype relative to control plants and methods of producing said transformed plant. However, the specification only provides a plant transformed with a nucleic acid encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 that when overexpressed produces a high oil phenotype in the plant. The specification does not identify any other sequences that produce a high oil phenotype, including any sequences that could be considered orthologs of HIO30. In addition, the specification does not describe any structural features of the polypeptides that are required to confer the claimed function of producing a high oil phenotype in a transformed plant. Applicants are claiming a genus of sequences. However, only one sequence has been provided.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

8. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plants comprising a plant transformation vector comprising

a sequence that encodes the HIO30 polypeptide comprising the amino acid sequence of SEQ ID NO: 2, wherein the transgenic plant has a high oil phenotype, does not reasonably provide enablement for a transgenic plant comprising a plant transformation vector comprising a sequence that encodes the HIO30 polypeptide that is an ortholog of the amino acid sequence of SEQ ID NO: 2, and wherein the transgenic plant has a high oil phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are drawn to transgenic plants comprising a plant transformation vector comprising a sequence that encodes HIO30 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or an ortholog thereof, and wherein the plant has a high oil phenotype relative to control plants and methods of producing said transformed plant.

9. The specification at page 11 defines orthologs of HIO30 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO30 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity, and preferably a pseudouridylate synthase domain. However, Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic

activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular catalytic activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least).

However, the specification does not set forth how expression of the HIO30 polypeptide confers a high oil phenotype on a transformed plant. The specification states that the functional activity of HIO30 and orthologs thereof may be any of a signaling activity, a binding activity, a catalytic activity or a cellular or extra-cellular localizing activity, and preferably having a pseudouridylate synthase domain. Yet none of these functional activities are demonstrated for SEQ ID NO: 2 or for any orthologs thereof, and the specification does not teach how to assay for any of these functional activities.

Thus, given the unpredictability of identifying sequences that exhibit the same functional activity and producing a high oil phenotype in a transgenic plant; the lack of guidance in the specification for the structural and functional characteristics of sequences that are orthologs of SEQ ID NO: 2 and will produce a high oil phenotype in a plant; and given the lack of working

examples of any sequences other than SEQ ID NO: 2 that will produce a high oil phenotype in a plant; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638